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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,287	01/11/2001	Raul G. Barletta	UNL 2999.01	9782

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SENNIGER POWERS LEAVITT AND ROEDEL  
ONE METROPOLITAN SQUARE  
16TH FLOOR  
ST LOUIS, MO 63102

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/17/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/759,287

Applicant(s)

BARLETTA ET AL

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 43-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.                      6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Applicants' Response to Restriction, received 25 January 2002, paper #7, is acknowledged.

Applicants elect, with traverse, Invention II, claims 15-42, drawn to composition comprising mutant whole bacteria, classified in class 424, subclass 248.1.

The traversal is on the grounds that any search for one inventions will necessarily co-extend with the search and examination of the other inventions, and also will not constitute undue burden upon the examiner.

This is not found persuasive because while the searches may overlap, each distinct invention requires addition searches of the particular methodology/reagents in each invention, and therefore, the searches are not coextensive.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-53 are pending. Claims 1-14 and 43-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.
3. Claims 15-42 are under consideration.

### **Specification**

4. The disclosure is objected to because of the following informalities:
  - a) it is recommended that Table 1 and Table 2 be titled in order to facilitate understanding of the tables' content,
  - b) in Table 1, the third column, "Ration" should be "Ratio",
  - c) page 25, line 18, "Cumulativce" should be "Cumulative",

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Appropriate correction is required.

### **Drawings**

5. This application has been filed with drawings which have been reviewed by the Draftsperson and found acceptable.

6. The following is a recitation of 37 C.F.R. §1.74, Reference to Drawings:

When there are drawings, there shall be a brief description of the several views of the drawings, and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures, and to the different parts by use of reference letters or numerals (preferably the latter).

The Brief Description of Figure 3 does not describe the individual graphs, 3A, 3B, 3C, and 3d.

7. Figure 2 is objected to under M.P.E.P. §2422.02, third paragraph, which recites that “the sequence identifier (“SEQ ID NO:X”) must be used, either in the drawing or in the Brief Description of the Drawings.” Figure 2 contains a sequence (TGTTAACG ggctcttcgca.....tgccaagagccTGTTAACG) which is not designated by a sequence identifier. Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to an antibiotic used at a concentration “between of at least 0.015 µg/ml.” It is unclear what concentration is used because there is no second limit of concentration which the chosen concentration can be “between”.

11. Claims 15-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mutants of *M. paratuberculosis*, does not reasonably provide enablement for vaccines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

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The nature of the invention - A composition for immunizing an animal against bacterial infection (i.e., vaccine composition) comprising  $\geq$  nonvirulent strain of bacteria which has been mutated by introducing  $\geq$  one mutation into the genome of a bacteria.

The state of the prior art - The art of mutation of bacteria is well known, and the art of mutation of *Mycobacteria* in particular has been increasing in the near past. However, even with the history of mutation of bacteria, there is a lack of predictability in the art for the particularly claimed invention.

The amount of direction or guidance present in the specification is insufficient to rectify the lack of predictability in the art because the specification does not provide any working examples of the claimed invention, i.e., vaccines comprising mutated bacteria. The instant specification provides guidance and one example of a mutated bacteria produced by the claimed methodology, i.e., mutated *M. paratuberculosis*. The specification teaches virulence testing of the mutated *M. paratuberculosis* in Beige mice. However, the specification does not provide any examples of the claimed invention, a vaccine, but merely recites a proposal of what is desired.

Thus, the instantly claimed inventions constitute merely an invitation to experiment without a reasonable expectation of success.

### **Conclusion**

12. No claims are allowed.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



RODNEY P SWARTZ, PH.D

PRIMARY EXAMINER

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April 15, 2002